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U.S. PATENT & TRADEMARK OFFICE

No. 03-1524
(Serial no. 09/597,608)

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

IN RE JOHN NGAI and DAVID LIN

APPEAL FROM THE UNITED STATES PATENT AND TRADEMARK
OFFICE, BOARD OF PATENT APPEALS AND INTERFERENCES

BRIEF FOR APPELLANTS JOHN NGAI and DAVID LIN

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September 26, 2003

CERTIFICATE OF INTEREST

1. The full name of every party represented by me is:

John Ngai and David Lin

2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by me is:

The Regents of the University of California

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party or amicus curiae represented by me are:

None

4. The names of all law firms and the partners or associates that appeared for appellant in the Patent and Trademark Office or are expected to appear in this Court are:

Richard Aron Osman, J.D., Ph.D.

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STATEMENT OF RELATED CASES

1. No appeal from the proceeding of the lower tribunal has been previously before this Court or any other appellate court.

2. There are no cases known to be pending in this or any other court that will directly affect or be directly affected by this Court's decision in the pending appeal.

STATEMENT OF JURISDICTION

1. The United States Patent and Trademark Office Board of Patent Appeals and Interferences had jurisdiction over this matter pursuant to 35USC§134.
2. This Court has jurisdiction over this appeal from the final decision of the United States Patent and Trademark Office Board of Patent Appeals and Interferences pursuant to 35USC§141.
3. This appeal was timely filed pursuant to 35USC§142.

STATEMENT OF THE ISSUES

Appellants seek review of a Decision of the Board of Patent Appeals and Interferences: in Appeal No. 2002-1092 re US Serial No. 09/597,608, the Board unanimously reversed rejection under 35USC§103(a) of claim 20, but affirmed on a split 2-1 vote rejection of claim 19 under 35USC§102(b). The only art cited against claim 19 is Stratagene Catalog, 1995, p.109 (A171). The only issue in this appeal is whether claim 19 was properly rejected under 35USC§102(b) in view of this Stratagene publication.

STATEMENT OF THE CASE

The subject patent application discloses and claims methods and corresponding kits for normalizing and amplifying RNA. All the method claims (Claims 1-18) were allowed; however, the two corresponding kit claims (Claims 19 and 20) were rejected under 35USC§102(b) and 35USC§103(a), respectively:

19. A kit for normalizing and amplifying an RNA population, said kit comprising instructions describing the method of claim 1 and a premeasured portion of a reagent selected from the group consisting of: oligo dT T7 biotinylated primer, T7 RNA polymerase, annealed

biotinylated primers, streptavidin beads, polyadenyl transferase, reverse transcriptase, RNase H, DNA pol I, buffers and nucleotides.

20. A kit according to claim 19, comprising premeasured portions of oligo dT T7 biotinylated primer, T7 RNA polymerase, annealed biotinylated primers, streptavidin beads, polyadenyl transferase, reverse transcriptase, RNase H, DNA pol I, buffers and nucleotides.

In Appeal No. 2002-1092 re US Serial No. 09/597,608, the Board unanimously reversed the rejection of claim 20, but affirmed on a split 2-1 vote the rejection of claim 19. The only art cited against claim 19 is Stratagene Catalog, 1995, p.109.

STATEMENT OF THE FACTS

The invention relates to a method for normalizing and amplifying an RNA population. This general method comprises the steps of:

- (a) copying message RNA (mRNA) to form first single-stranded (ss) cDNA;
- (b) converting the first ss-cDNA to first double-stranded (ds) cDNA;
- (c) linearly amplifying the first ds-cDNA to form first amplified RNA

(aRNA);

(d) tagging the 3' end of the first aRNA with a known sequence to form 3'-tagged first aRNA;

(e) copying the 3'-tagged first aRNA to form second ss-cDNA; and

(f) normalizing the mRNA or the first aRNA.

The only claim on appeal is directed to a kit for use in practicing this method. This kit comprises a premeasured portion a of biochemical reagent used in the method, and instructions describing the method as recited above.

This statement of the facts was provided to the Board in our Appeal Brief (Summary of the Invention; A48, lines 7 - 17).

SUMMARY OF THE ARGUMENT

Claim 19 is limited to a kit which requires particular instructions. The required instructions are not found in the cited art. Since the cited art does not disclose a required element of the claim, the claimed kit can not be anticipated by the cited art.

ARGUMENT INCLUDING STANDARD OF REVIEW

The substantial evidence standard of review is applicable (*Dickinson v.*

Zurko, 527US150, CAFC 1999).

The only cited art (Stratagene Catalog, 1995, p.109) does not provide a required element of claim 19 (the required instructions), and hence cannot anticipate the claim. The Examiner ignores an express limitation of our claim in order to encompass the cited art. In particular, the Examiner ignores the specifically required instructions, arguing that “no patentable weight is given to instructions describing a method (the instructions are considered to be merely printed matter)”.

The Examiner never has discretion to disregard claim limitations. Furthermore, the rejection is without legal supported. First, the cited *In re Haller* (161 F2d 280; CCPA 1947) decision was issued in 1947, prior to the enactment of the Patent Act of 1952, now codified in Title 35 of the United States Code. Second, neither the holding nor even the cited dicta of *Haller* supports the Examiner’s contention. And third, in *In re Gulack*, 703 F2d 1381 (CAFC 1983), the Federal Circuit again and emphatically reversed a Board contention that printed matter could not impart patentability:

Differences between an invention and the prior art cited against it cannot be ignored merely because those differences reside in the content of the printed matter.⁸ Under section 103, the board cannot

dissect a claim, excise the printed matter from it, and declare the remaining portion of the mutilated claim to be unpatentable. The claim must be read as a whole.

Gulack at p.1385.

The Court in *Gulack* pointedly expressed its frustration with rejections based on some notion that printed matter limitations may be ignored.¹

Not only is the Examiner's position inconsistent with applicable law, it is inconsistent with USPTO practice. A quick search of the USPTO patent database revealed hundreds of patents issued in the past few years that clearly rely on the printed matter limitation. We have of record highlighted claims sheets from 33 of these (A66-A107) that clearly rely on the very same kit/instructions combination

¹ Footnote 8 of *Gulack*: "A "printed matter rejection" under § 103 stands on questionable legal and logical footing. Standing alone, the description of an element of the invention as printed matter tells nothing about the differences between the invention and the prior art or about whether that invention was suggested by the prior art. A printed matter rejection is based on case law antedating the 1952 patent act, employing a point of novelty approach. *In re Sterling*, 70 F.2d 910, 21USPQ519 (CCPA 1934). The 1952 act legislatively revised that approach through its requirement that the claim be viewed as a whole in determining obviousness. *Graham v. John Deere Co.*, 383 U.S. 1, 148USPQ459 (1966). The CCPA has considered all of the limitations of the claims including the printed matter limitations, in determining whether the invention would have been obvious. See *In re Royka*, 490 F.2d 981, 180USPQ580 (CCPA 1974); *In re Cavrich*, 451F.2d1091, 172USPQ121 (CCPA 1971). *In Royka*, 490 F.2d at 985, 180 USPQ at 583, the CCPA, notably weary of reiterating this point, clearly stated that printed matter may well constitute structural limitations upon which patentability can be predicated."

as does our claim 19.² While Appellants recognize that the USPTO's conduct in other cases is not dispositive here, it informs the commonplace of such claims and raises the question of whether the agency is treating similar applicants similarly.

We believe the dispositive legal question is this: does an express requirement for particularly recited instructions merely define "an intent to use" that does not limit the claim? The opposing Board Opinions are self-explanatory. The Smith/Adams Opinion characterizes an express limitation as an intent to use and argues that this limitation (called "language" by the Smith/Adams Opinion) is not being ignored, just not given "patentable weight" (the term "patentable weight" does not appear in any patent statute). Apparently insecure with its reasoning, the Smith/Adams Opinion tosses a red herring, alleging that under the reasoning of the Grimes dissenting Opinion, any old composition could be repatented merely by labeling it with instructions describing the new use of the old composition (A10, lines 16-19). This rhetoric is inapplicable. No one is repatenting any old composition. Like almost all patent claims, ours claim a new combination (our kit) which includes an old composition.

² The Examiner's Answer questions whether the recited instructions of these issued claims are providing patentability. They clearly are. Even a cursory review of the claims readily demonstrates that without the instructions, the highlighted claims of all of these patents are plainly not novel. Even the one claim selected by the Examiner, claim 2 of US Pat No.6,177,407, would clearly read on prior art angiotensin but for the recited instructions.

The Grimes Opinion's reasoning, shared by Appellants, is simple: "Since every limitation of the claim must be considered, and since anticipation requires every limitation of the claim to be shown in the prior art, the examiner's concession that Stratagene does not disclose one of the limitations of the claimed kit compels the conclusion that Stratagene does not anticipate claim 19" (A17, lines 2-5). An intent to use would be recited as: '*A kit for use in our method*'. Our recited instructions are no more an intent to use than is the recited reagent. In fact, our claims are indifferent to how the kit is used, or if it is used at all.

Furthermore patentability of these instructions-coupled product claims is policy rational. As observed by the Grimes Opinion, "Appellants will soon have the legal right to exclude others from practicing the method of claim 1; I do not see that any purpose is served by denying them the right to exclude others from selling a kit comprising 'instructions describing the method of claim 1,' together with other components." (A25, line 24 - A26, line 3)

In fact, granting this kit claim is necessary to honor the quid pro quo of the patent system. Appellants have disclosed an innovative and commercially valuable method of manipulating RNA, and are accordingly entitled to corresponding patent rights to protect Appellants, for a limited time, from infringers who would commercially exploit their invention without license. The

structure of the biotechnology industry makes it difficult for Appellants to enforce their allowed method claims, wherein infringement typically occurs in closed laboratories and often by end-users with little financial stake in their infringement. The real exploiters here are the commercial vendors who make, market and profit from selling the kit. Should the Patent Law permit such an exploiter to misappropriate the invention without being liable for direct infringement, leaving the University of California only secondary, more tenuous theories of contributory or induced infringement? Furthermore, is a disclosed, but ultimately unclaimed kit dedicated to the public?

CONCLUSION AND RELIEF SOUGHT

Claims 19 is properly limited to a kit which requires particular instructions. The required instructions are not found in the cited art. Since the cited art does not disclose a required element of the claim, the claimed kit can not be anticipated by the cited art. We request reversal of the Board Decision sustaining rejection of claim 19.

Respectfully Submitted

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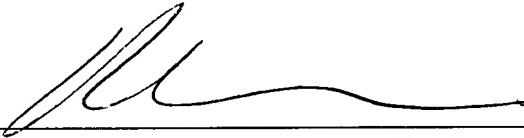
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PROOF OF SERVICE

I hereby certify that on September 26, 2003, I caused two copies of the foregoing Appeal Brief to be mailed by U.S. mail (first-class, postage prepaid), addressed as follows:

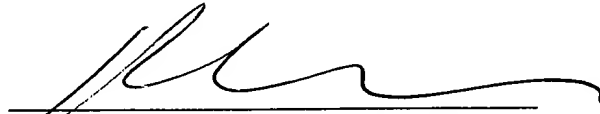
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CERTIFICATE OF COMPLIANCE

I certify that this brief is proportionately spaced, has a typeface of 14 points and contains 1,739 words according to the word count of the word-processing system used to prepare this brief.

A handwritten signature in black ink, appearing to read 'Richard Aron Osman', written over a horizontal line.

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